

PATENT CLAIMS

1. An application of monoclonal antibodies being specific for CD28 and activating T lymphocytes of several to all sub-groups without occupying an antigen receptor of the T lymphocytes and thus in an antigen-unspecific manner, or of an analogue thereto, for producing a pharmaceutical composition in an embodiment as a preparation or preparation package for treating virus infections of the human body or of body of a lower warm-blooded animal with infected T lymphocytes, wherein the pharmaceutical composition further contains a virus inhibitor.
- 15 2. An application according to claim 1, wherein CD4 T lymphocytes, in particular human CD4 T lymphocytes, are infected, and wherein the monoclonal antibodies are specific for human CD28 and the monoclonal antibodies are as an option well tolerated for human beings.
- 20 3. An application according to claim 1 or 2, wherein the virus infection is an infection caused by retrovirus, in particular lentivirus, for instance HIV.
- 25 4. An application according to claim 1 to 3, wherein the virus inhibitor is a reverse transcriptase inhibitor, preferably a pyrimidin nucleoside analogue, most preferably 3'-azido-3'-desoxythymidine (AZT or zidovudine), and as an option further other nucleoside analogues different therefrom, preferably 3TC, are included in the pharmaceutical composition.

5. An application according to claim 1 to 4, wherein the pharmaceutical composition further contains a protease inhibitor, and as an option further protease inhibitors different therefrom.

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6. A pharmaceutical composition in an embodiment as a preparation or preparation package, with pharmaceutical effective doses of the following drug components:

10 a) monoclonal antibodies preferably well tolerated for human beings, preferably being specific for CD28, preferably human CD28 and activating T lymphocytes, preferably human T lymphocytes, of several to all sub-groups without occupying an antigen receptor of the T lymphocytes and thus in an antigen-unspecific manner, or an analogue thereto,

15 b) a virus inhibitor, preferably a reverse transcriptase inhibitor,

c) as an option a reverse transcriptase inhibitor being different from b),

20 d) as an option a protease inhibitor,

e) as an option a protease inhibitor different from d).

7. A pharmaceutical composition according to claim 6,
wherein the drug components b) to e) are selected,
dosed and made ready to administer according to the
HAART therapy.

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8. A pharmaceutical composition according to claim 6 or 7,
wherein

the drug components drug component b) is a pyrimidin
nucleoside analogue, preferably 3'-azido-3'-
10 desoxythymidine, and/or

the drug component c) is 3TC, and/or

the drug component d) is provided in a conclusive
manner.

15 9. A pharmaceutical composition according to one of claims
6 to 8, wherein the drug components b) to e) are part
of a first package component, and the drug component a)
is part of a second package component.

20 10. A package component according to one of claims 6 to 9,
containing the drug component a).

11. A method for treating virus infections with retrovirus,
in particular, lentivirus, for instance HIV, wherein the
25 pharmaceutical composition according to claims 6 to 9
is administered to a human body or to the body of a
lower warm-blooded animal attacked by the infection.

✓ 12. A method for treating virus infections with retrovirus, in particular lentivirus, for instance HIV, wherein the following drug components are administered to a human body or to the body of a lower warm-blooded animal in 5 pharmaceutically effective doses:

10 a) monoclonal antibodies preferably well tolerated for human beings and being specific for CD28, preferably human CD28 and activating T lymphocytes, preferably human T lymphocytes of several or all sub-groups without occupying an antigen receptor of the T lymphocytes and thus in an antigen-unspecific manner, or an analogue thereto,

15 b) a virus inhibitor, preferably a reverse transcriptase inhibitor,

c) as an option a reverse transcriptase inhibitor different from b),

d) as an option a protease inhibitor,

e) as an option a protease inhibitor different from d).

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✓ 13. A method according to claim 12, wherein the drugs b) to e) are selected, dosed and administered according to the HAART therapy and wherein the drug component a) is administered before, together with or after the drug 25 components b) to e).

14. A method according to claim 12 *or* 13, wherein the drug components b) to e) are administered continuously and the drug component a) once or several times in time intervals with breaks.

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15. A method according to one of claims 12 to 14, wherein the drug component b) is a pyrimidin nucleoside analogue, preferably 3'-azido-3'-desoxythymidine, and/or

10 the drug component c) is 3TC, and/or the drug component d) is provided in a conclusive manner.

16. An application of a monoclonal antibody a) preferably well tolerated for human beings and being specific for CD28, preferably human CD28 and activating T lymphocytes, preferably human T lymphocytes of several or all sub-groups without occupying an antigen receptor of the T lymphocytes and thus in an antigen-unspecific manner, or an analogue thereto, and a virus inhibitor b), preferably a reverse transcriptase inhibitor in the form of a mixture or of spatially separated compositions, one of those containing the drug component a) and the other one containing the drug component b), as a means for continuous and/or discontinuous application during the treatment of virus infections with retrovirus, in particular lentiviruses, for instance AIDS, in human beings or lower warm-blooded animals according to a treatment plan comprising one or more cycles, the treatment plan comprising the following steps:

- i) first the drug component b) is continuously administered in a pharmaceutically effective dose,
- 5 ii) after a given time duration of step i) the drug component a) is administered in a pharmaceutically effective dose, with continued administration of the drug component b),
- 10 iii) as an option step ii) will be repeated once or several times after a given break period, with continued administration of the drug component b).

17. An application according to claim 16, wherein the administration of the drug component b) takes place by a treatment sub-plan being the HAART therapy.

18. An application, pharmaceutical composition, package component or method according to one of claims 1 to 17, wherein the monoclonal antibody is CMY-2, available from hybridom cells according to deposit DSM ACC2353, or the clone ANC28.1/5D10, or a preferably humanized or human-tolerated variant of the clone ANC28.1/ 5D10.